

§ 124.10

License applicant. Any person who, in accordance with part 102 of this chapter, submits an application to the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture for a U.S. Veterinary Biological Product License.

Patent. A patent issued by the Patent and Trademark Office of the United States Department of Commerce.

Person. Any individual, firm, partnership, corporation, company, association, educational institution, State or local government agency, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

PTO. The Patent and Trademark Office of the United States Department of Commerce.

[58 FR 11369, Feb. 25, 1993, as amended at 68 FR 6346, Feb. 7, 2003]

Subpart B—Eligibility Assistance

§ 124.10 APHIS liaison with PTO.

Upon receipt of a copy of an application for extension of the term of a veterinary biologic patent from PTO, APHIS will assist PTO in determining whether a patent related to a biological product is eligible for patent term extension by:

(a)(1) Verifying whether the product was subject to a regulatory review period before its commercial marketing or use;

(2) Determining whether the permission for commercial marketing or use of the product after the regulatory review period was the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred, and, if so, whether it was the first permitted commercial marketing or use of the veterinary biological product for administration to a food-producing animal;

(3) Ascertaining whether the patent term restoration application was submitted within 60 days after the product was approved for marketing or use; and

(4) Providing such other information as may be necessary and relevant to PTO's determination of whether a patent related to a product is eligible for patent term restoration.

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(b) APHIS will notify PTO of its findings in writing, send a copy of this notification to the applicant, and make a copy available for public inspection in room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Subpart C—Regulatory Review Period

§ 124.20 Patent term extension calculation.

(a) As provided in 37 CFR 1.779 of PTO's regulations, in order to determine a product's regulatory review period, APHIS will review the information in each application to determine the lengths of the following phases of the review period, and will then find their sum:

(1) The number of days in the period beginning on the date authorization to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was initially submitted under the Virus-Serum-Toxin Act; and

(2) The number of days in the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(b) A license application is "initially submitted" on the date it contains sufficient information to allow APHIS to commence review of the application. A product license is issued on the date of the APHIS letter informing the applicant of the issuance. The issuance of a license releases the product for commercial marketing or use.

§ 124.21 Regulatory review period determination.

(a) Not later than 30 days after the receipt of an application from PTO, APHIS shall determine the regulatory review period. Once the regulatory review period for a product has been determined, APHIS will notify PTO in writing of the determination, send a copy of the determination to the applicant, and make a copy available for public inspection in room 1141, South